

**DEPARTMENT OF FOOD AND AGRICULTURE**

## INITIAL STATEMENT OF REASONS

**Hearing Date:** No public hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture no later than 15 days prior to the close of the written comment period.

**Subject Matter of Proposed Regulations:** Pasteurization Requirements and Pasteurization Equivalency

**Section(s) Affected:** Adopt Section 581

**Specific Purpose of Each Adoption, Amendment, or Repeal**

Existing Law, Food and Agricultural Code section 34001 sets forth the requirements for pasteurizing milk and provides specific heating times and temperatures. This section also authorizes the Department of Food and Agriculture (Department) to review and approve processes of milk pasteurization that have been demonstrated to be equally efficient as those processes specified in section 34001.

Food and Agricultural Code section 32515 specifies that the term "pasteurized" means that the milk or milk product has been subjected to a process that is described in Chapter 8 (commencing with section 34001), or other process which has been demonstrated to be equally efficient and has been approved by the Department.

In compliance with section 34001, et seq., the Department has in place requirements for operators of pasteurization equipment under sections 582, 583, 584, and 585 of Article 19, of Chapter 1, Division 2 of Title 3 of the California Code of Regulations. However, these requirements do not allow for the consideration of alternatives to pasteurization pursuant to sections 34001 and 32515.

Therefore, the Department is adopting new section 581 to update Article 19 of Chapter 1, Division 2 of Title 3 of the California Code of Regulations to designate the requirements for pasteurization, and allow for uniform evaluation of pasteurization equivalency consistent with current technology and research. This proposal specifies the method for the public to submit proposals to the Department for review and determination of equivalency to authorized pasteurization technologies. This proposal will also make California consistent with federal definitions of pasteurization and ensure that California's milk regulatory program complies with the Grade "A" Pasteurized Milk Ordinance, 2003 Revision, of the United States Department of Health and Human Services, Public Health Service/Food and Drug Administration.

## **Factual Basis**

The Department's Milk and Dairy Food Safety Branch is charged with the mission and responsibility of ensuring that California's milk, milk products, and products resembling milk products are safe and wholesome, and meet microbiological and compositional requirements before the products enter the marketplace.

The Milk and Dairy Food Safety Branch provides training and supervision for local Approved Milk Inspection Services to develop statewide uniformity. Dairy Foods Specialists inspect dairy farms and milk processing plants, and collect samples of milk and milk products to ensure consumer safety as well as check fail-safe systems on pasteurization equipment, and evaluate dairy farms, milk plants, and laboratories for the United States Food and Drug Administration (FDA) for the safety of dairy products in interstate commerce.

The Department's Dairy Foods Specialists inspect each of the milk processing plants monthly and once each quarter a more comprehensive inspection is conducted in which conditions at each plant is scored. There are currently 376 milk pasteurization units in California operating in 140 milk processing plants. Revenue to fund this program is generated by licensing and inspection fees and assessments on milk production per gallon pursuant to sections 33295 and 33296 of the Food and Agricultural Code.

Pursuant to Food and Agricultural Code section 34001, the Department is authorized to approve processes which have been demonstrated to be equally efficient to pasteurization. The Department's regulations, under Article 19 of Chapter 1, Division 2, of Title 3 of the California Code of Regulations, relating to pasteurization have not been amended to keep current with research findings and new pasteurization technology. Current industry practice and federal law allows for a variety of time-temperature combinations for pasteurization that have been determined equally effective to those cited in section 34001 for denaturing pathogenic organisms in milk and milk products.

Milk is a rich nutrient medium for microorganisms and, without pasteurization, may contain organisms that transmit disease to humans such as tuberculosis, listeriosis, salmonellosis, typhoid fever, bacillary dysentery, diphtheria, streptococcal infection, or brucellosis. Pasteurization is the most critical step in milk processing to assure the safety of milk and dairy products. Alternative but equivalent methods of pasteurization will allow industry to make use of more effective technology, creating energy and resource savings for the industry and maintaining lower consumer prices for milk and dairy products.

The Milk and Dairy Food Safety Branch is the only state agency with comprehensive expertise, experience and training in the dairy industry from farm to table, including milk pasteurization technology and laboratory issues unique to the dairy industry. Therefore, the Department has determined that the following pasteurization requirements are approved for use in California, and the following criteria will be used for evaluating proposals for pasteurization equivalency:

## Adopt section 581 - Pasteurization Requirements and Equivalency.

Subsections (a) through (a)(1)(A) clarify the pasteurization times and temperatures currently acceptable to the Department pursuant to sections 32515 and 34001 of the Food and Agricultural Code. The methods described ensure that the milk and milk product is free from pathogenic organisms harmful to humans.

Subsections (b)(1) through (8) establish the method of application for equivalency of new pasteurization technologies. The public may submit their proposals for equivalency in a manner of their choosing and no specific form is required. However, the proposal must contain the information specified in subsections (b)(1) through (8). The proposal must include, at a minimum, a detailed description of the process, scientific data, charts or diagrams, technical reviews and evaluations, as available, to enable the Department to make a determination of equivalency. Also accepted would be data published by the National Conference on Interstate Milk Shipments (NCIMS). The NCIMS is made up of representatives from state and local dairy regulatory agencies, FDA, USDA, industry, laboratories and academia. The main thrust of the Conference is to deliberate proposals addressing food safety issues to ensure that the dairy products we consume are safe.

Subsection (c) is needed to inform the public that the Department shall acknowledge receipt of the proposal within 30 business days. The Department believes this time frame is adequate so the person or organization submitting the proposal will be informed that their proposal has been received and is under evaluation.

Subsection (d) provides information to the public on how the Department shall determine equivalency. The Department shall evaluate the information received [according to subsections (b)(1) through (8)], on a case-by-case basis. No specific time period or deadline for the Department to issue its decision on equivalency is specified in this proposal. This is due to the variances in each proposal. Some of the proposed equivalency processes may take several months to complete studies or pilot programs, while other proposals may take longer due to the technology or evolving issues not yet identified at this time.

## **Underlying Data**

All the federal and NCIMS information referenced in this proposal pertaining to milk pasteurization is found in the Grade "A" Pasteurized Milk Ordinance (PMO), 2003 Revision, United States public Health Service/Food and Drug Administration Publication. The PMO is a guidance document published by the FDA recommending requirements for the dairy industry to ensure uniformity in standards for safe and wholesome dairy products. A copy is available via the Internet at <http://www.cfsan.fda.gov>, or by contacting the FDA or the Department.

### **Business Impact**

This proposal would not have significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This proposal does not impose any fees, nor requires changes to existing milk and milk products plants in California. This proposal affects individuals and businesses choosing to apply to the Department for approval of alternatives to pasteurization as defined in Food and Agricultural Code section 34001.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment, but establishes the process by which the effectiveness and safety of new and innovative technologies may be evaluated by the Department.

### **Consideration of Alternatives**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department of Food and Agriculture would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.